

REMARKS

I. STATUS OF THE CLAIMS

Claims 45-63 are pending. Claims 51 and 53 are withdrawn from consideration. Claims 52, 61, and 62 are canceled. Claims 45-50, 54-60, and 63 are currently under examination.

II. OBJECTIONS

A. Objections to New Matter

1. Sentrin-specific protease comprising the amino acid sequence PIH^L/_RXVHW

The Action objects to claiming a sentrin-specific protease comprising the amino acid sequence PIH^L/_RXVHW where X is a glycine, lysine, or glutamic acid as being new matter. Applicants respectfully traverse.

Sentrin-specific protease amino acid sequences comprising the amino acid sequence PIH^L/_RXVHW where X is a glycine, lysine or glutamic acid are provided in the specification's sequence listing as SEQ ID NO:2, SEQ ID NO:8, and SEQ ID NO:10, as well as the parent application serial number 09/628,966. Furthermore, alignment of various sentrin-specific proteases are provided in Table 5 of the specification demonstrating the presence of the PIH^L/_RXVHW amino acid sequence in a number of sentrin-specific proteases. Applicants note that the claims are directed to a sentrin-specific protease comprising the amino acid sequence of PIH^L/_RXVHW. Therefore, claim 45 is supported by the disclosure of the parent application and does not contain new matter. Applicants request the withdrawal of the objection.

2. Objection to Claims 52, 61, and 62

Claims 52, 61, and 62 are objected to as containing new matter. Claims 52, 61, and 62 are canceled without prejudice. The objection is moot.

B. Objection to Sequence Identifiers

The Action objects to the lack of sequence identifier for the subsequence $\text{PIH}^{\text{L}}/\text{R}\text{XVWH}$ where X is glycine, lysine, or glutamic acid. It is generally acceptable to present a single, general sequence in accordance with the sequence rules and to discuss and/or claim variants of that general sequence without presenting each variant as a separate sequence in the “Sequence Listing.” MPEP § 2422.03. Applicants note that the amino acid sequence cited in the claim is an amino acid component defining variant polypeptides of the claimed sentrin-specific proteases. Therefore, a separate sequence identifier is not necessary. Applicants request withdrawal of the rejection.

III. REJECTIONS UNDER 35 USC § 112

A. Claims 45-54, 61, and 62 Satisfy the Written Description Requirement

The Action rejects claims 45-54, 61, and 62 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement based on the alleged lack of written description for a sentrin-specific protease comprising the amino acid sequence $\text{PIH}^{\text{L}}/\text{R}\text{XVHW}$ where X is glycine, lysine, or glutamic acid. Applicants respectfully traverse.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP § 2163 citing for example *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Applicants have provided description in the specification from which one skilled in the art would reasonably conclude that applicants had possession of a sentrin-specific protease (SENP) polypeptide comprising the amino acid sequence $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ where X is glycine, lysine, or glutamic acid. Sentrin-specific protease amino acid sequences are provided in the specification's sequence listing as SEQ ID NO:2, SEQ ID NO:8, and SEQ ID NO:10, each of which comprise an amino acid sequence of $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ where X is a glycine, lysine, or glutamic acid. Furthermore, alignment of various sentrin-specific proteases are provided in Table 5 and figure 7 of the specification, demonstrating the presence of the $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ amino acid sequence in a number of sentrin-specific proteases.

Therefore, Applicants have described a sentrin-specific protease polypeptide in a manner that would reasonably convey to one of skill in the art that the inventors were in possession of a sentrin-specific protease comprising an amino acid sequence of $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ where X is a glycine, lysine, or glutamic acid. Applicants respectfully request the withdrawal of the rejection.

B. Claims 45-50 and 55-60 satisfy the written description requirement

The Action rejects claims 45-50 and 55-60 as failing to comply with the written description requirement based on Applicants alleged failure to exemplify or describe the preparation or discovery of the polypeptide described by claims 45-50 and 55-60 to the extent these products differ from the structure of SEQ ID NO:2. Applicants respectfully traverse.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP § 2163 citing for example *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Applicants describe a sentrin-specific protease in such sufficient detail that one skilled in the art can reasonably conclude that inventor was in possession of an isolated sentrin-specific protease. Claim 45 is directed to “An isolated sentrin-specific protease (SEN) polypeptide comprising the amino acid sequence $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$, wherein X is a glycine, lysine, or glutamic acid.” Applicants have provided description in the specification from which one skilled in the art would reasonably conclude that applicants had possession of a sentrin-specific protease (SEN) polypeptide comprising the amino acid sequence $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ where X is glycine, lysine, or glutamic acid. Sentrin-specific protease amino acid sequences are provided in the specification’s sequence listing as SEQ ID NO:2, SEQ ID NO:8, and SEQ ID NO:10, each of which comprise an amino acid sequence of $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ where X is a glycine, lysine, or glutamic acid. Furthermore, alignment of various sentrin-specific proteases are provided in Table 5 and figure 7 of the specification, demonstrating the presence of the $\text{PIH}^{\text{L}}/\text{R}^{\text{XVHW}}$ amino acid sequence in a number of sentrin-specific proteases.

Applicants do not fully understand the reasoning set forth in the Action. For example, the Action improperly implies an admission on the part of the inventors by stating that SENP-1 cannot cleave sentrin-1 from RanGAP1. This statement is not entirely correct. SENP-1 does not cleave sentrin-1 from Ran GAP1 in the context of cell culture because the SENP-1 is localized in the nucleus and RanGAP1 is non-nuclear (specification page 86 lines 8 to 18). Applicants note that lack of cleavage is most likely due to cellular localization of RanGAP1 and not a lack of protease activity. Nonetheless, the relevance of sentrin-1 cleavage from RanGAP1 is unclear.

Also unclear is the Action’s reliance on *Fiers v Revel*. The relevance of *Fiers v Revel* is suspect at best because Fiers was relying on a method of isolating a DNA for description of the DNA itself. Thus, the court statement related to “particularity” is relevant to a generic

description of a DNA molecule with no underlying nucleic sequence available. Applicants are at a loss to explain the relevance of this case to this application.

Applicants respectfully request the withdrawal of the rejection.

C. Claims 45-50 and 55-60 are Enabled

The Action rejects claims 45-50 and 55-60 under 35 U.S.C. § 112 for lacking enablement based on an alleged insufficient teaching of how the amino acids of a sentrin-specific protease may be altered yet provide a protease with the disclosed utility. Applicants respectfully traverse.

It is well settled that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. MPEP § 2164 citing *e.g., In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In light of the description provided in the specification, one of skill in the art could make and use sentrin-specific proteases of the invention with minimal experimentation. Applicants have satisfied the requirements of 35 U.S.C. § 112 as they related to enablement of the invention. Applicants describe a number proteins identified as sentrin-specific proteases, for example the specification page 21 lines 15-24 reads:

[T]he inventors have identified the SENP1 gene. . . . For example, the gene may be expressed to obtain and SENP1 polypeptide as set forth in SEQ ID NO:2. It is contemplated that any composition or method discussed with respect to SEQ ID NO:2, may be implemented with respect to SEQ ID NO:8 and/or SEQ ID NO:10.

The specification also provide guidance as to the production of sentrin-specific protease variants, for example on page 24 lines 20 to 26 that read:

In one embodiment, amino acid sequences variants of the polypeptide can be prepared. . . . They also may be sequences that do not occur naturally but that are sufficiently similar that they function similarly [] with natural forms of the polypeptide.

Furthermore, the specification describes a variety of assay to assess sentrin-specific protease function, for example in Example 3, Example 4, and FIG. 5 demonstrate an assay for detecting sentrin-specific protease activity. One of skill in the art would readily be able, with undue experimentation, to produce and identify an isolated sentrin-specific protease polypeptide comprising the amino acid sequence PIH^L/_RXVHW where X is glycine, lysine or glutamic acid.

IV. REJECTIONS UNDER 35 USC § 102

The Action rejects claims 55-58 under 35 U.S.C. § 102(b) as anticipated GenBank Accession numbers AA236084, AA236014, or AA330056. Applicants respectfully traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The DNA fragments described in the database entries cited as anticipating claims 55-58 do not describe a sentrin-specific protease SENP1. Claim 55 is directed to “An isolated polypeptide comprising a sentrin-specific protease SENP1.” In contrast, GenBank accession number AA236084, AA236014, or AA330056 describe a 345 bp, a 382 bp, and a 274 bp nucleic acid fragment, respectively. Applicants note, that none of these GenBank entries provide any information related an amino acid sequence. Applicants are at loss as to how a nucleic acid fragment is interpreted as teaching each and every element of sentrin-specific protease SENP1. Nonetheless, a peptide fragment does not anticipate the polypeptide from which it has been derived. By definition a fragment cannot described each and every element of the whole, thus peptide cannot anticipate a polypeptide. Applicants note that the Action’s allegation of a lack of

any requirement for a structure permitting function is irrelevant. A peptide still cannot anticipate the polypeptide from which it was derived.

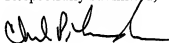
Applicants respectfully request the withdrawal of the anticipation rejections of claims 55-58.

CONCLUSION

Applicants believe that the present document is a full and complete response to the Action dated September 25, 2006. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Agent at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: January 25, 2007